Recommendation No. 144/2021
of 30 December 2021
of the President of the Agency for Health Technology Assessment and Tariff System
on the assessment of Cosentyx (secukinumab)
under the drug programme [information protected as a trade secret]

The President of the Agency recommends the reimbursement of Cosentyx (secukinumab) under the drug programme [information protected as a trade secret]

The President of the Agency does not recommend the reimbursement of Cosentyx (secukinumab) under the drug programme [information protected as a trade secret] as proposed in the application.

Grounds for the recommendation

Currently, secukinumab therapy as part of the treatment of severe plaque psoriasis is financed by the public payer in the population of patients aged more than 18 under the B.47 drug programme "Treatment of moderate and severe form of plaque psoriasis (ICD-10 L 40.0)". The assessed application concerns the extension of the reimbursement for Cosentyx [information protected as a trade secret]

The performed clinical analysis in the form of a randomised clinical trial proves a statistically significant advantage of secukinumab (SEK) over [information protected as a trade secret] in terms of improving skin condition (according to PASI 75/90/100 index and the IGA scale). The obtained results concern patients with severe plaque psoriasis; therefore, it should be taken into account that there are no data on a direct comparison of the efficacy of SEK in the population of patients with a moderate form of that disease. [information protected as a trade secret]

[information protected as a trade secret]

The conclusions of the budget impact analysis were also taken into account, which clearly indicate that the reimbursement of the assessed technology will lead to [information protected as a trade secret]

Moreover, it should be emphasised that a positive decision on the reimbursement of treatment [information protected as a trade secret]

Taking the above arguments into account, the reimbursement of secukinumab [information protected as a trade secret]

Subject of the application

The order of the Minister of Health concerns the assessment of the appropriateness of public reimbursement of the following medicinal product:

- Cosentyx (secukinumab), solution for injection in a pre-filled syringe, 150 mg/ml, 2, pre-filled syringe 1 ml, GTIN code: 05909991203832, for which the proposed net sales price is [information protected as a trade secret]
- Cosentyx (secukinumab), solution for injection in an injector, 300 mg, 1, injector, GTIN code: 07613421040130, for the proposed net sales price is [information protected as a trade secret] under the drug programme [information protected as a trade secret]

Proposed payment and dispensing category: free of charge under the drug programme, in the existing limit group 1180.0, secukinumab. The applicant has submitted a proposal for a risk-sharing scheme.

Health problem

Psoriasis (ICD-101: L.40.0) is an autoimmune, chronic, recurrent and multifactorial inflammatory skin disease with a course that is difficult to predict; it is characterised by keratinocyte hyperproliferation and the infiltration of immune cells such as T lymphocytes, dendritic cells, macrophages and neutrophils.

Characteristic symptoms of psoriasis are skin lesions in the form of pinkish-red spots covered with yellowish or silvery scales. The spots may combine and cover a significant area of the skin. The lesions are most often located around knees and elbows, on the extensory parts of limbs, in the sacrum area and on the hairy scalp.

The incidence of psoriasis in adults ranges from 0.51% to 11.43% of the population, while in children, it ranges from 0 to 1.37%. The greatest number of cases of psoriasis is observed in white people (especially in Northern Europe). Psoriasis occurs at the same frequency in both genders, with persons of any age possibly developing the disease. Psoriasis is not a life-threatening disease, but it significantly affects person's quality of life and functioning in society.

Alternative health technology

Taking into account clinical guidelines and currently publicly-funded technologies, the comparator for the proposed technology is [information protected as a trade secret]

Description of the proposed intervention

Secukinumab is a human IgG1/κ class monoclonal antibody that selectively binds to and neutralises the pro-inflammatory cytokine, interleukin-17A (IL-17A).

According to the Summary of Product Characteristics (SmPC), Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy. [information protected as a trade secret]

Treatment of severe plaque psoriasis with secukinumab is currently financed in adult patients in Poland under the B.47. drug programme Treatment of moderate to severe plaque psoriasis (ICD-10: L40.0).

Efficacy, effectiveness and safety assessment

This assessment involves collecting data on the health consequences (efficacy and safety) of the new therapy for the health problem in question and of other therapies that are currently reimbursed from

public funds and represent alternative therapies available for the health problem. Furthermore, this assessment requires determination of the reliability of data collected and a comparison of the efficacy and safety results of the new therapy against the therapies already available to treat the health problem in question.

On the basis of the above, the efficacy and safety assessment allows answering the question of the scale of the health outcome (both in terms of efficacy and safety) to be expected from the new therapy compared with other therapeutic options under consideration.

The efficacy and safety of secukinumab was assessed in the population of [information protected as a trade secret]

The clinical analysis included: [information protected as a trade secret]

No studies were identified that performed a direct comparison of the assessed intervention with [information protected as a trade secret]
in the population of patients with moderate plaque psoriasis. The purpose of the comparison of SEK results [information protected as a trade secret] [information protected as a trade secret] it was not possible to make a reliable indirect comparison).

The reliability of the study [information protected as a trade secret] was assessed with the use of the Cochrane descriptive scale criteria. [information protected as a trade secret]

In the study, the following endpoints were mainly assessed:

- Response to treatment as measured using the PASI 50/75/90[1] scale;
- Response to treatment as measured using the IGA (or PGA) 0/1[2] scale;

[information protected as a trade secret]

Efficacy

Direct comparison of SEK vs [information protected as a trade secret] (severe plaque psoriasis)

Quality of life [information protected as a trade secret]

PASI 75/90/100 (improvement in skin condition by at least 75%/90% or by 100%), IGA 0-1 (healthy, almost healthy skin) [information protected as a trade secret]

[information protected as a trade secret]

Safety [information protected as a trade secret]

No statistically significant differences between SEK and [information protected as a trade secret] safety were demonstrated in terms of the analysed endpoints concerning safety. [information protected as a trade secret]

Comparison of SEK data vs [information protected as a trade secret]

1 PASI (Psorasis Area Severity Index) is an index that takes into account the extent and severity of skin lesions. The severity assessment is made based on three disease symptoms: erythema (E), infiltration (I) and scale build-up (D) on a scale from 0-4 (where 0 means no severity, 1- low severity, 2 - moderate severity, 3 - high severity and 4 - maximum severity) and the affected area in four locations - head, trunk, upper limbs, lower limbs ranging from 0 (< 10%) to 6 (90-100%). The maximum score is 72 points. The higher the score, the more severe psoriasis.

2 IGA (Investigator's Global Assessment, Modified 2011) or PGA (Physician's Global Assessment of Psoriasis) is an assessment of the general health condition of patients with psoriasis performed by a doctor/researcher. The scale ranges from 0 to 5 points, where 0 means no lesions and 5 means severe disease
[information protected as a trade secret]

Additional information

According to SmPC for Cosentyx, the safety profile of SEK is consistent across all recommendations assessed to date. Very common (≥1/10) adverse effects of SEK include: upper respiratory tract injections. Common adverse effects (≥1/100 to <1/10) are: oral herpes, tinea pedis, headache, watery nasal discharge, diarrhoea, nausea, fatigue.

Information on important identified side effects of Cosentyx were found on the EMA website, which include infections and hypersensitivity reactions.

Limitations

The reliability of conclusions is mainly affected by the lack of studies directly comparing the efficacy and safety of Cosentyx with the selected comparator [information protected as a trade secret]

Furthermore, there are no studies allowing an indirect comparison to be made so the analysis of the results in this population is based only on putting them together.

It should also be noted that there are no data on the long-term efficacy of the drug - the longest follow-up period is 52 weeks (for the general population), while the results of the comparison of SEK and [information protected as a trade secret]

Proposed risk-sharing scheme [information protected as a trade secret]

Economic evaluation, including a cost-effectiveness estimation

Economic evaluation involves estimating and comparing the costs and health outcomes that may be associated with the administration of the new therapy to an individual patient instead of already reimbursed therapies.

The costs of therapy are estimated in Polish currency, and health outcomes are usually expressed in life-years gained (LYG) or quality-adjusted life years (QALY) as a result of the therapy.

Juxtaposing the values concerning the costs and outcomes of a new therapy and comparing them to the costs and outcomes of already reimbursed therapies allows answering the question of whether the health outcome achieved in an individual patient owing to a new therapy is associated with a higher cost in comparison with already reimbursed therapies.

The obtained results of the cost-effectiveness ratio are compared with the so-called cost-effectiveness threshold, i.e. a result that indicates that given the wealth of Poland (expressed in GDP), the maximum cost of the new therapy that is expected to produce a unit of health outcome (1 LYG or 1 QALY) compared to already available therapies should not exceed three times GDP per capita.

Currently, the cost-effectiveness threshold is PLN 166,758 / QALY (3 x PLN 55,586).

The cost-effectiveness ratio does not estimate or determine the value of life, but it only enables its assessment and on that basis, among other things, choosing the therapy related to potentially best outcome.

Cost-utility analysis (CUA) was performed for the time horizon from the beginning of treatment under the programme until the patient reaches adulthood (in the model, it is approximately 4 years), from the public payer perspective – the entity obliged to finance the interventions from public funds, i.e. the National Health Fund (NHF) and from the joint perspective – the National Health Fund (NHF) and the beneficiary (patient).

The assessed intervention, i.e. secukinumab (SEK), was compared with [information protected as a trade secret]

The following categories of medical costs were included in the analysis:

- costs of drugs and their administration,

- costs of qualifying for the programme, diagnosis and monitoring of treatment,
- costs of adjuvant treatment.

The ICUR, from the NHF perspective, was: [information protected as a trade secret]

The application of SEK is [information protected as a trade secret] .The estimated values of ICUR exceed the cost-effectiveness threshold referred to in the Reimbursement Act.

With the ICUR value estimated in the basic analysis, the threshold value of the net sales price of the drug is [information protected as a trade secret]

All variants of the sensitivity analysis confirm the conclusions obtained in the basic variant. The greatest changes in the incremental cost [information protected as a trade secret]

The results of the probabilistic analysis proved that the probability of the cost-effectiveness of the SEK therapy is [information protected as a trade secret]

Limitations [information protected as a trade secret]

Agency's own calculations

No additional own calculations were performed.

Indication whether the circumstances referred to in Art. 13 sec. 3 of the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices (Dz. U. /Journal of Laws/ of 2021, item 523 as amended) do arise.

If the applicant's clinical analysis does not include randomised clinical trials proving the superiority of the drug over health technologies already reimbursed, the official selling price of the drug must be calculated so that the cost of the drug to be reimbursed is not higher than the cost of the health technology with the most favourable cost–effectiveness ratio.

The clinical analysis does not include randomised clinical trials proving the superiority of the applied technology over the comparator, [information protected as a trade secret]

Assessment of the impact on the healthcare system, including the budget impact

Healthcare system impact assessment has two major parts.

First, the analysis of the impact on the payer's budget allows estimating the potential expenses associated with public reimbursement of the new therapy.

Estimates of the expenses associated with the new therapy (the "tomorrow" scenario) are compared to how much is currently spent on treating the health problem (the "today" scenario). On this basis, it is possible to assess whether a new therapy will require more resources allocated to the treatment of the given health problem or whether it will result in savings in the payer's budget.

A budget impact assessment determines whether a payer has adequate resources to reimburse a particular technology.

The assessment of the impact on the healthcare system, in the second section, is an answer to the question of how the decision to finance the new therapy may affect the organisation of the provision of interventions (particularly in the context of adjusting the system to the requirements related to the provision of the new therapy) and the availability of other healthcare interventions.

The results of the applicant's budget impact analysis are presented taking into account a two-year horizon. The analysis was performed from the public payer (NHF) perspective. [information protected as a trade secret]

The analysis included the costs of drugs and their administration, the costs of assessing eligibility for the programme, diagnosis and monitoring of treatment and the costs of adjuvant treatment.

The applicant has estimated the patient population that will use the proposed technology at: [information protected as a trade secret]

The results of the basic analysis of the applicant reveal that the reimbursement of the assessed technology in the proposed indication, [information protected as a trade secret]

Limitations

The main limitations of the analysis relate to the assumptions [information protected as a trade secret]

Agency's own calculations

No additional own calculations were performed.

Comments on the proposed risk-sharing scheme [information protected as a trade secret]

Comments on the drug programme

Currently, secukinumab therapy is financed by the public payer in the population of persons over 18 years old under the B.47 drug programme "Treatment of moderate and severe forms of plaque psoriasis (ICD-10 L 40.0)" but only for severe plaque psoriasis. [information protected as a trade secret]

Discussion on the solutions proposed in the rationalisation analysis

The subject of the rationalisation analysis is the identification of a mechanism, the introduction of which will result in the release of public funds in an amount corresponding to at least the increase in costs resulting from a positive decision on the reimbursement of the health technology covered in this recommendation.

The rationalisation analysis is submitted if the budget impact analysis for the entity responsible for funding indicates an increase in reimbursement costs.

Overview of recommendations in relation to the assessed technology

Clinical recommendations were identified. They were issued by:

- Polish Dermatological Society (PTD 2020);
- European Dermatology Forum (EDF 2021);
- National Institute for Health and Care Excellence (NICE 2021);
- British Association of Dermatologists (BAD 2020); [information protected as a trade secret]

Furthermore, publications [information protected as a trade secret] (Belgian recommendation) and [information protected as a trade secret] (Italian recommendation) were included.

To sum up, according to the existing guidelines, it is recommended to use secukinumab for [information protected as a trade secret]

[information protected as a trade secret]

Reimbursement recommendations

As a result of the search, 4 reimbursement recommendations, issued in 2021, were identified. [information protected as a trade secret]

According to the information provided by the applicant, Cosentyx is financed in [information protected as a trade secret] EU and EFTA (out of 31 indicated).

Legal basis for the recommendation

The recommendation was prepared under the order of the Minister of Health of 4 June 2021 (ref. no.: PLR.4500.1584.2020.11.RBO) concerning the preparation of the President's recommendation on the assessment of Cosentyx (secukinumab) under the drug programme [information protected as a trade secret] pursuant to Art. 35 sec. 1 of the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs intended for particular nutritional uses and medical devices (Dz. U. /Journal of Laws/ of 2021, item 523 as amended), having obtained Position of the Transparency Council No. 144/2021 of 27 December 2021 on the assessment of Cosentyx (secukinumab) under the drug programme: [information protected as a trade secret]

References

1. Position of the Transparency Council No. 144/2021 of 27 December 2021 on the assessment of Cosentyx (secukinumab) under the drug programme: [information protected as a trade secret]

2. Report No. OT.4231.53.2021 Application for the reimbursement of Cosentyx (secukinumab) under the drug programme [information protected as a trade secret] Completion date: 16 December 2021.